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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/520,325 | 09/12/2005 | Kevin Woehr | 1131-14-PCT-PA-TD | 5105 |
| 22145 7590 01/19/2010 KLEIN, O'NEILL & SINGH, LLP 43 CORPORATE PARK SUITE 204 IRVINE, CA 92606 | | | EXAMINER ANDERSON, MICHAEL J | |
| | | | ART UNIT 3767 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,325

Applicant(s)

WOEHR, KEVIN

Examiner

MICHAEL J. ANDERSON

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 10-26 is/are allowed.
6) ☒ Claim(s) 1-4 and 9 is/are rejected.
7) ☒ Claim(s) 5-8 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 04 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

In view of the Appeal Brief filed on 10/28/2009, PROSECUTION IS HEREBY REOPENED. New Grounds of rejection set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Kevin C. Simmons/

Supervisory Patent Examiner, Art Unit 3767

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bialecki (US 6,652,486) in view of Tauschinski (US 4,387,879).

With regards to claim 1, Bialecki discloses (figures 1-10) catheter insertion device comprising a hollow catheter hub (22) having a catheter tube (28, 31) attached at a distal end thereof, a needle hub (24) having a hollow needle (38) attached thereto and extending through the catheter hub and the catheter tube when in a ready position (figure 1), a needle guard element (26) arranged displaceably on the needle in the catheter hub and having an engaging section (72, 98) which engages with an engaging means (44) formed near the needle tip when the hollow needle is removed from the catheter hub (figures 9 and 10). However, Bialecki does not disclose wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in, the ready position and which automatically closes after the removal of the needle, and wherein the check valve remains in the catheter hub when the hollow needle is removed from the catheter hub and the catheter tube. Tauschinski discloses (figures 1-4) a check valve (7) for use in the distal end of a catheter hub (1). Therefore it would have been obvious to a person of

ordinary skill in the art at the time the invention was made to modify the catheter hub of Bialecki (Bialecki has space between the guard and the catheter tube as seen in figure 5) as disclosed by Tauschinski for providing a self sealing valve to block fluid flow.

With regards to claim 2 Bialecki and Tauschinski disclose the device according to claim 1, and Tauschinski further discloses wherein the catheter hub comprises a distal hub element (6) and a proximal hub element (2), and the check valve is held between the distal hub element and the proximal hub element, which are joined to one another (figure 2).

With regards to claim 3, Bialecki and Tauschinski disclose the device according to claim 1 and Tauschinski further discloses wherein the check valve has a plurality of radially elastically expandable valve flaps (3, 8, figure 3) configured to be moved into an open position by fluid pressure generated from a syringe (this would be inherent give enough fluid pressure).

With regards to claim 4, Bialecki and Tauschinski disclose the device according to claim 1 and Bialecki further discloses wherein the catheter hub comprises an inner circumference and a radial projection (34) projecting radially from the inner circumference which is configured to engage with the needle guard element in the ready position (figure 1).

With regards to claim 9, Bialecki and Tauschinski disclose the device according to claim 1 and Bialecki further discloses wherein the needle guard element (26) is formed as a spring clip which has diametrically opposite spring arms (96 and 100) starting from a rear wall provided with a bore (72), wherein bent end sections (98 and

102) of the spring arms overlap and block the needle tip (figures 8 and 9) when the engaging means of the needle comes to abut on the rear wall.

Response to Amendment

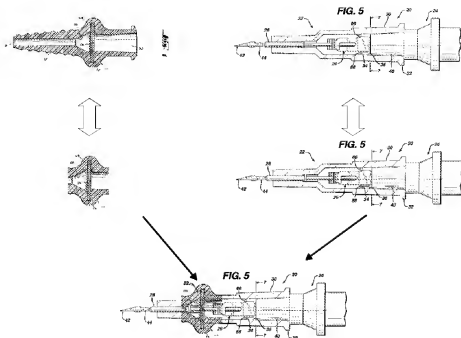
The present communication responds to the Amendment of 10/28/2009. By this communication, no claims were amended. The amendments did not add new matter. Claims 1-26 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments filed 6/25/2009 have been fully considered but they are not persuasive. It is noted that applicant did not provide arguments for claims 1-4 and 9 in the appeal brief filed on 10/28/2009.

To address applicants' arguments with regards to claim 1, note the Examiners "combo device" (see figures below) is not as depicted by applicants arguments on 6/25/2009 regarding the "combo device" figure on page 13.

Analysis:



With regards to applicants' arguments concerning claims 1, the 103(a) rejections states "....However, Bialecki does not disclose wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in, the ready position and which automatically closes after the removal of the needle, and wherein the check valve remains in the catheter hub when the hollow needle is removed from the catheter hub and the catheter tube. Tauschinski discloses (figures 1-4) a check valve (7) for use in the distal end of a catheter hub (1). Therefore it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the catheter hub of Bialecki (Bialecki has space between the guard and the catheter tube as seen in figure 5) as disclosed by Tauschinski for providing a **self** sealing valve to block fluid flow.

As for applicants' arguments, the combination of Bialecki and Tauschinski discloses *"wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position:"* and *"wherein the check valve remains in the catheter hub when the hollow needle is removed from the catheter hub and the catheter tube"*.

In response to applicant's argument that the combined components of Bialecki (figure 1 above) and Tauschinski (figure 5 above), are not compatible, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant's arguments, see pages 5-27, filed 10/28/2009, with respect to claims 5-8 and 10-26 have been fully considered and are persuasive. The 103(a) rejections of claims 5-8 and 10-26 have been withdrawn.

Allowable Subject Matter

Claims 5-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 10-26 are allowed.

The following is an examiner's statement of reasons for allowance: The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. With regards to independent claims 10 and 11, the prior art does not disclose or render obvious "a valve actuating element" in combination with the other limitations of the independent claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ANDERSON whose telephone number is (571)272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Anderson/
Examiner
Art Unit 3767

MJA
1/15/2010
/Kevin C. Simons/
Supervisory Patent Examiner, Art Unit 3767